

**REMARKS**

This Amendment makes editorial changes to claims 17, 18, 22, 27 and 30. Claims 17-22, 25-28, 30, 33 and 34 are pending.

This Amendment overcomes the 35 U.S.C. § 112, second paragraph, rejection of claims 17-22, 25-28, 30, 33 and 34. More particularly, claims 17, 18 and 30 have been amended to recite that which is measured ("total PAPP-A bound to said first binder" and "PAPP-A complexed to proMBP bound to said second binder"). Claim 22 has been amended to provide antecedent basis for subsequent claim terms, and to eliminate any ambiguity regarding the PAPP-A/proMBP complex.

Independent claims 17 and 18 recite active, positive steps, such as "exposing", "detecting", "calculating", "comparing" and "diagnosing". It is respectfully submitted the statute does not require method claims to conclude with a step relating the method result to the purpose of the method. Indeed, the inventors are entitled to claim their invention as they see fit where, as here, one of ordinary skill in the art would understand the metes and bounds of the claims. Reconsideration and withdrawal of the indefiniteness rejection of claims 17-22, 25-28, 30, 33 and 34 are respectfully requested.

The 35 U.S.C. § 102(b) rejection of claims 27 and 28 over U.S. Patent No. 6,500,630 to Conover et al. is respectfully traversed. A feature of the claimed methods is the analysis of free PAPP-A, rather than complexed PAPP-A, in a sample and its use as a marker for acute coronary syndrome.

Conover et al. fails to disclose the use of free PaPP-A as a marker for acute coronary syndrome. See the attached declaration by Dr. Pettersson, which demonstrates the experiments in Conover et al. are based on antibodies which detect total PAPP-A rather than exclusively free PAPP-A.

Importantly, if Conover et al. had realized that exclusively free PAPP-A is a better marker than total PAPP-A, they could have determined exclusively free PAPP-A as "total PAPP-A" minus "proMBP-complexed PAPP-A" using antibodies which were available on their application date<sup>1</sup>. Conover et al.'s failure to analyze for exclusively free PAPP-A proves they did not realize that exclusively free PAPP-A is a better marker for ACS diagnosis.

In short, Conover et al. does not disclose or suggest the use of exclusively free PAPP-A as marker for acute coronary syndrome.

---

<sup>1</sup> Mabs 234-2, 234-3, 234-4, 234-5 and 234-6 measure total PAPP-A, while mabs 234-8 and 234-10 detect proMBP; for 234-8 and 234-10 see Article 2 of the thesis by Qin, page 5, paragraph 3.2 and Table 1.

Reconsideration and withdrawal of the anticipation rejection of claims 27 and 28 over Conover et al. are respectfully requested.

A Supplemental Information Disclosure Statement is attached, and submits the documents discussed in Dr. Pettersson's Declaration which are not already of record.

It is believed this application is in condition for allowance. Reconsideration and withdrawal of all rejections of claims 17-22, 25-28, 30, 33 and 34, and issuance of a Notice of Allowance directed to those claims, are respectfully requested. The Examiner is urged to telephone the undersigned should he believe any further action is required for allowance.

The fees for the extension of time and Supplemental IDS are being paid electronically today. It is not believed any additional fee is required for entry and consideration of this Amendment.

U.S. Patent Appln. S.N. 10/580,329  
AMENDMENT

**PATENT**

Nevertheless, the Commissioner is authorized to charge Deposit  
Account No. 50-1258 in the amount of any such required fee.

Respectfully submitted,

/James C. Lydon/

James C. Lydon  
Reg. No. 30,082

Atty. Case No.: **OHMAN-010**  
100 Daingerfield Road  
Suite 100  
Alexandria, Virginia 22314  
Telephone: (703) 838-0445  
Facsimile: (703) 838-0447

Enclosures:

Petition for Extension of Time  
Supplemental Information Disclosure Statement  
Declaration Pursuant to 37 C.F.R. § 1.132